DEPARTMENT OF HEALTH & HUMAN SERVICES
New York District

Food & Drug Administration
300 Pearl Street, Suite 100
Buffalo, NY 14202

M3672N

April 18, 2000

WARNING LETTER NYK 2000-65

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Masashi Yoshida
President and CEO
The Mentholatum Co., Inc.
707 Sterling Drive
Orchard Park, New York 14127

Dear Mr. Yoshida:

During an inspection of your facility located at 707 Sterling Drive, Orchard Park, New York, on 10/22-11/3/99 U. S. Food and Drug Administration (FDA) Investigator Patricia A. Clark collected a sample of Migraine Ice™ and copies of product labeling. Review of the labeling for the Migraine Ice™ revealed the product is in serious violation of the Federal, Food, Drug, and Cosmetic Act (the Act).

Your product is not exempt from premarket notification (Section 510(k)) requirements, under Title 21 Code of Federal Regulations 890.5700 "cold pack", because it is intended to be used for headaches and for migraine relief. These intended uses are different from the intended uses of the devices that are classified in 890.5700 as cold packs. Because you do not have marketing clearance from FDA, marketing your product is in violation of the law. In legal terms, the product is adulterated under Section 501(f)(1)(B) because you did not obtain market approval based on information you developed which shows your device is safe and effective.

We have received notice [redacted] FDA's Center for Devices and Radiological Health (CDRH) Office of Device Evaluation. You indicate in your letter to us dated February 17, 2000, that you are continuing to market Migraine Ice™. Please be advised that until your firm receives notice from CDRH clearing this device for commercial distribution, Migraine Ice™ Cooling Headache Pads are adulterated within the meaning of Section 501(f)(1)(B) of the FD&C Act. They are Class III devices under Section 513(f), which do not have an approved application for premarket approval in effect pursuant to 515(a) or an approved application for an investigational device exemption under Section 520(g).

You should know that this is a serious violation of the law, which may result in FDA taking regulatory action without further notice to you. These actions include, but are not limited to seizing your product inventory, obtaining a court injunction against further marketing of the product, or assessing civil money penalties. Also, other Federal agencies are informed about the warning letters we issue, such as this one, and they may consider this information when awarding contracts.

You should notify this office in writing within fifteen (15) working days of receipt of this letter of the specific steps you have taken to correct the noted violations, including an explanation of each step being taken to prevent the recurrence of similar violations. If corrective action cannot be completed within 15 working days, state the reason for the delay and the time within which corrections will be completed. Your response may be directed to Lisa M. Utz, Compliance Officer, at the above address.

Sincerely,

Brenda J. Holman
District Director